

REMARKS/ARGUMENTS

Reconsideration of this Application and entry of this Amendment after Final are respectfully requested. The proposed amendment places the claims in better form for appeal. Additionally, this amendment addresses items brought up by the Examiner in the final office action. In view of the amendments and following remarks, favorable consideration and allowance of the application is respectfully requested.

Claims 20 and 56-72 were previously withdrawn as a result of earlier restriction requirements and are canceled herein in response to this final office action without prejudice to Applicant's right to pursue the subject matter of these claims in one or more related applications. Claims 2, 5, 13, 14 and 20-54 have been canceled. Claims 1, 3, 6, 12, 18, 19 and 55 are amended as discussed further below and new claims 73-76 have been added. New claim 73 finds support in previously filed claim 1. New claims 74-76 finds support in paragraph 0033 of the specification. No new matter was introduced as a result of the claim amendments.

35 U.S.C. §101 Rejections

Claims 1, 3-19 and 55 stand rejected under 35 U.S.C. §101 because the claimed invention is directed to non-statutory subject matter. Claims 1 and 55 has been amended to claim the reservoir "adapted for implantation adjacent to an aneurysm site." Claims 5, 13 and 14 have been canceled.

Based on the above-referenced amendments to claims 1 and 55, Applicants respectfully assert that amended and pending claims 1, 3, 4, 6-12, 15-19 and 55 are not directed to non-statutory subject matter and request the withdrawal of the 35 U.S.C. §101 rejection of these claims.

35 U.S.C. §112 Rejections

Claims 1, 3-19 and 55 stand rejected under 35 U.S.C. §112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Applicants have amended claim 1 to claim, in part “a reservoir adapted for implantation adjacent to an aneurysm site.” Claims 5, 13 and 14 have been canceled. Therefore, Applicants respectfully assert that the amended and pending claims 1, 3, 4, 6-12, 15-19 and 55 are not indefinite under 35 U.S.C. §112, second paragraph, and request that the Examiner withdraw the rejection on this basis.

Claims 1, 3-19 and 55 stand rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement.

Claims 5, 13 and 14 have been canceled. Furthermore, claim 1 has been amended to remove the requirement for a carrier. Dependent claim 73 has been added to claim a reservoir further comprising a carrier. Claims 3 and 12 have been amended to depend from new claim 73 and claim 6 has been amended to refer only to a reservoir. Therefore, Applicants respectfully assert that the amended and pending claims 1, 3, 4, 6-12, 15-19, 55 and new claim 73 comply with the written description requirement under 35 U.S.C. §112, first paragraph, and request that the Examiner withdraw the rejection on this basis.

35 U.S.C. §102 Rejections

Claims 1, 3-6, 9, and 11-19 stand rejected under 35 U.S.C. §102(b) as anticipated by Urquhart, US 3,797,485.

A claim is anticipated under 35 U.S.C. §102 only if each and every element as set forth in a claim is found, either expressly or inherently described, in a single prior art reference (MPEP §2131; *Verdegaal Bros. V. Union Oil Co. of California*, 814 F.2d, 628, 631, 2 USPQ2d 1051 (Fed. Cir. 1987)).

Amended independent claim 1 claims a device for the treatment of aneurysmal tissue, comprising: at least one reservoir; at least one therapeutic agent within said reservoir; and wherein the reservoir is adapted for implantation within or adjacent to an aneurysm site within a vessel lumen and delivers at least one therapeutic agent to said aneurysm tissue for the treatment of said aneurysmal tissue.

Urquhart discloses a drug delivery device disposed on the adventitial surface of a blood vessel for administering a drug into the blood stream by diffusion of a drug released on the adventitial surface across the vessel tissue into the blood stream. Urquhart does not disclose a drug delivery device disposed within the vessel lumen for release of a drug at an aneurysm site. Furthermore, an object of the device of Urquhart is to delivery drugs via diffusion through blood vessel walls without any mechanical penetration of the blood vessel wall by the drug delivery device (column 3, lines 13-17).

Applicants have amended claim 1 to recite a device comprising a reservoir disposed within a vessel lumen. New claims 74-76 have been added to claim a device comprising a reservoir disposed outside of the vessel lumen and connected to the vessel by means of a pump and tubing. The tubing of claims 74-76 requires the piercing of the blood vessel wall to convey the therapeutic agent from the reservoir to an aneurysmal site on luminal side of the blood vessel wall. Claims 5, 13 and 14 have been canceled as discussed *supra*.

Urquhart does not disclose the invention claimed in pending claims 1, 3, 4, 6, 9, 11, 12, 15-19 and new claims 74-76. Urquhart does not disclose a drug delivery device wherein the reservoir is disposed within the vessel lumen or alternatively, wherein the reservoir is located outside the vessel lumen and drug is delivered to the luminal surface of the aneurysm tissue by means of a pump and tubing, and therefore does not disclose each and every element of the drug delivery device claimed in amended and pending claims 1, 3, 4, 6, 9, 11, 12, 15-19 and 74-76. Therefore, Applicant respectfully requests that the rejection under 35 U.S.C. §102(b) be withdrawn.

35 U.S.C. §103 Rejections

Claims 1 and 3-19 stand rejected under 35 U.S.C. §103(a) as obvious over Urquhart, US 3,797,485; and claim 55 stands rejected under 35 U.S.C. §103(a) as being unpatentable over Urquhart '485 in view of Leonhardt et al, US 5,713,917. Applicants respectfully submit that the Examiner has not established *prima facie* obviousness of the pending claims in view of the cited references as discussed further *infra*.

To reject a claim under 35 USC §103(a), the Examiner bears the initial burden of showing an invention to be *prima facie* obvious over the prior art. See *In re Bell*, 26 U.S.P.Q.2d 1529 (Fed. Cir. 1992). If the Examiner cannot establish a *prima facie* case of unpatentability, then without more the applicant is entitled to grant of the patent. See *In re Oetiker*, 24 U.S.P.Q.2d 1443 (Fed Cir. 1992). The Examiner must meet a three-part test to render a claimed invention *prima facie* obvious.

To begin with, the prior art references cited by the Examiner must provide “motivation, suggestion, or teaching of the desirability of making the specific combination that was made by the application.” See *In re Kotzab*, 55 U.S.P.Q.2d 1316 (Fed. Cir. 2000). Where one reference is relied upon by the Examiner, there must be a suggestion or motivation to modify the teachings of that reference. See *id.* Where an obviousness determination relies on the combination of two or more references, there must be some suggestion or motivation to combine the references. See *WMS Gaming Inc. v. International Game Technology*, 51 U.S.P.Q.2d 1386 (Fed. Cir. 1999). The suggestion may be found in implicit or explicit teachings within the references themselves, from the ordinary knowledge of one skilled in the art, or from the nature of the problems to be solved. See *id.*

Second, the prior art references cited by the PTO must suggest to one of ordinary skill in the art that the invention would have a reasonable expectation of success. See *In re Dow Chemical*, 5 U.S.P.Q.2d 1529 (Fed. Cir. 1988). The expectation of success, like the motivation to combine two prior art references, must come from the prior art, not the applicant’s disclosure. See *id.*

Finally, the Examiner must demonstrate that the prior art references, either alone or in combination, teach or suggest each and every limitation of the rejected claims, See *In re Gartside*, 53 U.S.P.Q.2d 1769 (Fed. Cir. 2000).

If any one of these three factors is not met, the PTO has failed to establish a *prima facie* case of obviousness and the applicant is entitled to grant of a patent without making any affirmative showing of non-obviousness.

The Examiner has rejected claims 1 and 3-19 under 35 U.S.C. §103(a) as obvious over Urquhart, US 3,797,485. As stated *supra*, Urquhart discloses a drug delivery device disposed on the adventitial surface of a blood vessel for administering a drug into the blood stream by diffusion of a drug released on the adventitial surface across the vessel tissue into the blood stream. Urquhart does not disclose a drug delivery device disposed within the vessel lumen for release of a drug at an aneurysm site. Furthermore, a goal of the device of Urquhart is to delivery drugs via diffusion through blood vessel walls without any mechanical penetration of the blood vessel wall by the drug delivery device.

Amended independent claim 1 recites a device comprising a reservoir disposed within a vessel lumen and new claims 74-76 claim a device comprising a reservoir disposed outside of the vessel lumen and connected to the vessel by means of a pump and tubing. Urquhart does not teach or suggest each and every limitation of independent claims 1 and 74 as Urquhart discloses neither a drug delivery reservoir disposed within a vessel lumen nor an external device which delivers a therapeutic agent to aneurysm tissue by means of a pump and tubing. Furthermore, there is no motivation to modify the invention of Urquhart to produce the Applicant's claimed invention since the stated object of Urquhart's invention is to locate a drug delivery device external to a blood vessel to deliver a drug by diffusion across the vessel wall without piercing the vessel wall. Therefore, the Examiner has not established a *prima facie* case of obviousness of independent claims 1 and 74, and therefore dependent claims 3, 4, 6-11, 14-19, and 75-76, over Urquhart and Applicants respectfully request that the Examiner withdraw this ground of rejection.

The Examiner has rejected claim 55 under 35 U.S.C. §103(a) as being unpatentable over Urquhart '485 in view of Leonhardt et al, US 5,713,917.

As discussed *supra*, independent claim 1 is not obvious in view of Urquhart. Because claim 55 depends from claim 1 and therefore incorporates all the elements of claim 1, claim 55 is also not obvious over Urquhart as discussed *supra*.

The disclosure of Leonhardt does not cure the deficiencies of Urquhart. Leonhardt teaches stent grafts, and methods to deploy stent grafts. Leonhardt does not teach or suggest a

drug delivery device comprising a reservoir disposed within the vessel lumen for release of a drug at an aneurysm site and a stent graft adapted to be located at the aneurysm site.

In view of the foregoing, Applicant respectfully submits that neither of Urquhart or Leonhardt, either alone or in combination, teach or suggest a drug delivery device comprising a reservoir disposed within the vessel lumen for release of a drug at an aneurysm site and a stent graft adapted to be located at the aneurysm site. Therefore, Applicant respectfully submits that the cited references do not teach each and every element of claim 55 and therefore the PTO cannot establish *prima facie* obviousness of these claims. Accordingly, Applicant respectfully submits that claim 55 is not obvious under 35 USC § 103(a) and earnestly request the withdrawal of the outstanding rejection on this basis.

Conclusion

For the foregoing reasons, Applicant believes all the pending claims are in condition for allowance and should be passed to issue. The Commissioner is hereby authorized to charge any additional fees which may be required under 37 C.F.R. 1.17, or credit any overpayment, to Deposit Account No. 01-2525. If the Examiner feels that a telephone conference would in any way expedite the prosecution of the application, please do not hesitate to call the undersigned at telephone (707) 566-1888.

Respectfully submitted,

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